(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 February 2002 (14.02.2002)

PCT

(10) International Publication Number
WO 02/11774 A1

(51) International Patent Classification[7]: A61L 2/20, 2/24

(21) International Application Number: PCT/GB01/03459

(22) International Filing Date: 1 August 2001 (01.08.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0019215.3 4 August 2000 (04.08.2000) GB

(71) Applicant *(for all designated States except US)*: **BIOQUELL UK LIMITED** [GB/GB]; Walworth Road, Andover, Hampshire SP10 5AA (GB).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **DRINKWATER, James, Lindsay** [GB/GB]; Hollytree Cottage, Hollytree Lane, Cuddingston, Aylesbury, Buckinghamshire HP19 0BA (GB).

(74) Agent: **BOULT WADE TENNANT**; Verulam Gardens, 70 Gray's Inn Road, London WC1X 8BT (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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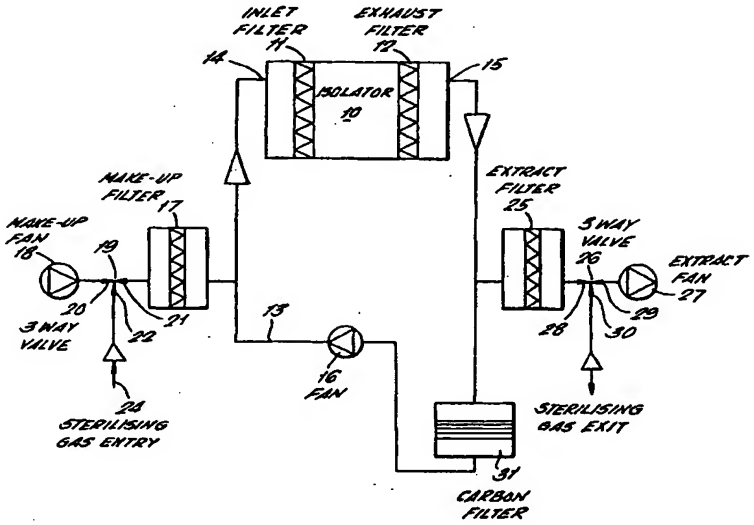
[Continued on next page]

(54) Title: METHOD OF STERILISING A SEALABLE ENCLOSURE



(57) Abstract: The disclosure relates to a method of sterilising a sealable enclosure comprising the steps of initially adjusting the relative humidity in the enclosure to a level substantially below ambient, circulating a carrier gas to the enclosure at a temperature raised above ambient at a first flow rate, supplying a sterilant vapour or vapours to the circulating carrier gas sufficient to saturate substantially the gas whereby, on cooling in the enclosure, a condensate of the sterilant vapour is formed on surfaces in the enclosure. Circulation of the gas/vapour is continued for a sufficient period of time to ensure sterilisation of the enclosure and any contents of the enclosure by the condensate which has been formed. Supply of sterilant vapour to the circulating gas is then terminated and circulation of the gas is continued at a second much higher flow rate, whilst removing sterilant vapour from the circulating gas to remove the sterilant from the enclosure.

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FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

— *of inventorship (Rule 4.17(iv)) for US only*

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

METHOD OF STERILISING A SEALABLE ENCLOSURE

The invention relates to a method for the rapid removal of a sterilising gas from an isolator.

In most gaseous sterilisation processes the longest part of the cycle is the removal of the active gas after the sterilisation has been achieved. All of the gases used for sterilisation are harmful to man and must therefore be reduced to a safe concentration before access is gained to the sterilised zone.

A further consideration is the damage that may be caused to products by exposure to low concentrations of sterilising gas.

It is therefore important that such gases are removed, but the removal to low concentrations is normally only achieved by flushing the chamber with a large amount of fresh air. The problem of the removal of the sterilising gas is made more difficult by the absorption of the gas into the surface of the chamber. The absorbed gas must then be removed and diluted to achieve a safe level before any processing is recommenced. The removal of the gas may take place in a number of ways. It may be decomposed in a catalytic system attached to the sterilising gas generator, or it may be expelled to the outside.

Expelling high concentrations of harmful and polluting gases to the environment is becoming a less acceptable solution. Decomposing the gas in the generator will take a considerable time because the airflow rates are those required to generate the gas, and these are quite small.

This invention provides a method of sterilising a sealable enclosure comprising the steps of initially adjusting the relative humidity in the enclosure to a level substantially below ambient, circulating a carrier gas to the enclosure at a temperature raised above ambient at a first flow rate, supplying a sterilant vapour or vapours to the circulating carrier gas sufficient to saturate substantially the gas whereby, on cooling in the enclosure, a condensate of the sterilant vapour is formed on surfaces in the enclosure, continuing to circulate the gas/vapour for a sufficient period of time to ensure sterilisation of the enclosure and any contents of the enclosure by the condensate formed, terminating supply of sterilant vapour to the circulating gas and finally circulating the gas at a second much higher flow rate and removing said sterilant vapour from the circulating gas to remove the sterilant from the enclosure.

Thus the solution to the problem is to make use of the very high airflow rates possible within the isolator. If this very high circulating airflow within the isolator is passed through a device to remove the active gas then clean air can be re-circulated to the isolator, thus quickly removing the active gas from the chamber.

The most common of the sterilising gases in the pharmaceutical industry is hydrogen peroxide because of the speed at which it kills micro-organisms and it does not leave any residues. Certain forms of catalytic carbon may decompose hydrogen peroxide gas and it is therefore possible to manufacture a device to remove the hydrogen peroxide gas from the very high circulating airflow using a catalytic carbon filter.

In the case where the sterilant vapour or vapours comprise hydrogen peroxide vapour and water vapour, both hydrogen peroxide and water vapours may be removed from the carrier gas in said final circulating of the gas.

In the above method the final rate of circulation of the carrier gas is some 40 times the first rate of circulation of the gas.

In the above method, there may be one flow path for the circulation of gas at said first rate and a second flow path for circulation at the second rate.

More specifically the second flow path may include a catalytic convertor to break down hydrogen peroxide into water vapour and oxygen and a fan for carrying the carrier gas to flow through said second path.

The following is a description of a specific embodiment of the invention, reference being made to the diagrammatic drawing of an isolator and decontamination circuit.

The diagram shows the main components of a simple laminar flow isolator system. An isolator 10 is fitted with an inlet filter 11, which covers the whole of one face of the isolator chamber (a side as shown but normally the top) to generate a down-flow of air which is vertical and laminar. The opposite face (again the other side as shown but normally the base) of the isolator houses an exhaust filter 12 in order to assist in maintaining the air flow as near as possible laminar. For practical reasons it may not be possible to have the exhaust filter extending over the whole of the base area of the isolator. Other arrangements may then be made to extract the air as near the base as possible. In some cases another face of the isolator, i.e. not the base

may be used for air extraction.

The isolator is connected in a circuit 13 having an inlet 14 to the isolator and an outlet 15 from the isolator. The air is delivered around the circuit and through the isolator by a fan 16. The normal airflow circulation generated by fan would be sufficient to give a laminar airflow velocity inside the chamber about 0.3m/s. Typically the length of the air path through the chamber will be about 900mm giving a passage time of the air through the isolator of 3 seconds or 20 air changes per minute or 1200 air changes per hour.

To remove any gaseous contamination which may build up inside the chamber and/or to maintain a stable temperature, provision is made to introduce some fresh air into the circuit 13 near to the inlet 14. Air may be introduced through a make-up filter 17, the air being supplied by a make-up fan 18 via a three-way valve 19 having a port 20 connected to the fan, a port 21 connected to the filter and a port 22 connected to a supply 24 of sterilising gas for initally charging the current with gas.

In order to maintain the correct pressure balance inside the isolator a similar amount of air to that added by the make-up fan 18 must be extracted from the circuit and this is removed through an extract filter 25 via a three-way valve 26 to an extract fan 27. The three-way valve has one port 28 connected to the filter, one port 29 connected to the extract fan for air removed from the system and one port 30 for sterilising gas removed from the circuit. The make-up fan 18 and extract fan 26 therefore maintain the flow of fresh air to the isolator and also the required pressure balance.

When it is required to sterilise the surfaces inside the isolator 10 the position of the three-way

valve 18 is adjusted to connect the supply of sterilising gas via the valve to filter 17 and thence circuit 13. A similar change is made to the three-way valve 26 giving a flow path from filter 25 through port 28 and thence port 29 to an exit for sterilising gas.

Some recent developments in surface sterilisation technology have shown faster deactivation of surface contamination by injecting the sterilising gas directly into the chamber. This requires that the sterilant is delivered into the chamber and distributed within the chamber before it cools.

Following sterilisation it is necessary to remove the active gas. This would normally be performed either by passing the air through the gas generator which will decompose the active gas or supply fresh air through the make-up fan 18. Both of these systems have a limited flow rate causing the time to remove the active gas to be extended.

The present device uses the circulatory fan 16 to circulate the air through the isolator 10. A catalytic carbon filter 31 is placed in the circulating airflow down stream of the exhaust filter 12. This catalytic carbon filter decomposes the active gas in the circulating airflow thus returning clean air to the isolator through the inlet filter 11. As explained earlier the re-circulating airflow will change the air in the isolator 10 in excess of 1000 times per hour, considerably faster than the fresh make-up air or the air supplied from the gas generator.

The greater increased flow of clean air dramatically reduces the time to reduce the active gas concentration in the isolator 10 to a safe level, returning it to use in a much shorter time.

CLAIMS

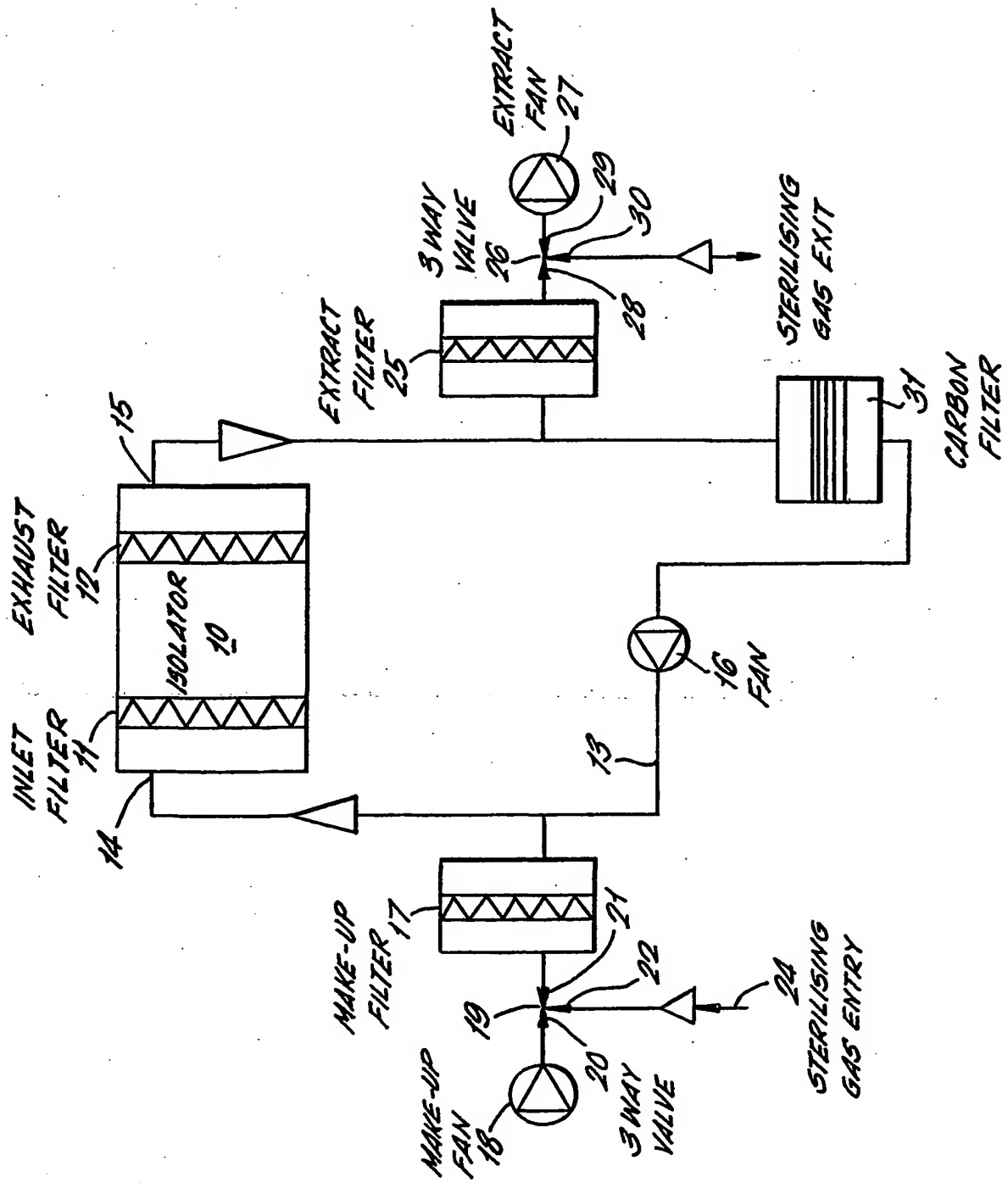
1. A method of sterilising a sealable enclosure comprising the steps of initially adjusting the relative humidity in the enclosure to a level substantially below ambient, circulating a carrier gas to the enclosure at a temperature raised above ambient at a first flow rate, supplying a sterilant vapour or vapours to the circulating carrier gas sufficient to saturate substantially the gas whereby, on cooling in the enclosure, a condensate of the sterilant vapour is formed on surfaces in the enclosure, continuing to circulate the gas/vapour for a sufficient period of time to ensure sterilisation of the enclosure by the condensate formed, terminating supply of sterilant vapour to the circulating gas and finally circulating the gas at a second much higher flow rate and removing said sterilant vapour from the circulating gas to remove the sterilant from the enclosure.

2. A method as claimed in claim 1 or claim 2, wherein the sterilant vapour or vapours comprise hydrogen peroxide vapour and water vapour and both hydrogen peroxide and water vapours are removed from the carrier gas in said final circulating of the gas.

3. A method as claimed in claim 1 or claim 2, wherein the second rate of circulation of the carrier gas is substantially greater than (e.g. 40 times) the first rate of circulation of the gas.

4. A method as claimed in any of the preceding claims, wherein there is one flow path for the circulation of gas at said first rate and a second flow path for circulation at the second rate.

5. A method as claimed in claim 4, wherein the second flow path includes a catalytic convector to break down hydrogen peroxide into water vapour and oxygen and a fan for carrying the carrier gas to flow through said second path.



INTERNATIONAL SEARCH REPORT

Int ial Application No
PCT/GB 01/03459

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L2/20 A61L2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	WO 97 47331 A (AMERICAN STERILIZER CO) 18 December 1997 (1997-12-18) page 7, line 18 -page 11, line 32; figures 6,7	1-5
A	EP 0 774 263 A (MDH LTD) 21 May 1997 (1997-05-21) column 5, line 47 -column 10, line 51; figure 1	1-5
A	US 4 898 713 A (PICARD CLAUDE) 6 February 1990 (1990-02-06) column 3, line 3 -column 6, line 6; figure 1	1-5

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 October 2001	17/10/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Edmueller, P

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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